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(71) Applicant *(for all designated States except US)*: CARMEL PHARMA AB [SE/SE]; P.O. Box 5352, S–402 28 Göteborg (SE).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: WESSMAN, Göran [SE/SE]; Örgryte Stomgata 14 B, S–412 67 Göteborg (SE).

(74) Agent: GÖTEBORGS PATENTBYRÅ DAHLS AB; Sjöporten 4, S–417 64 Göteborg (SE).

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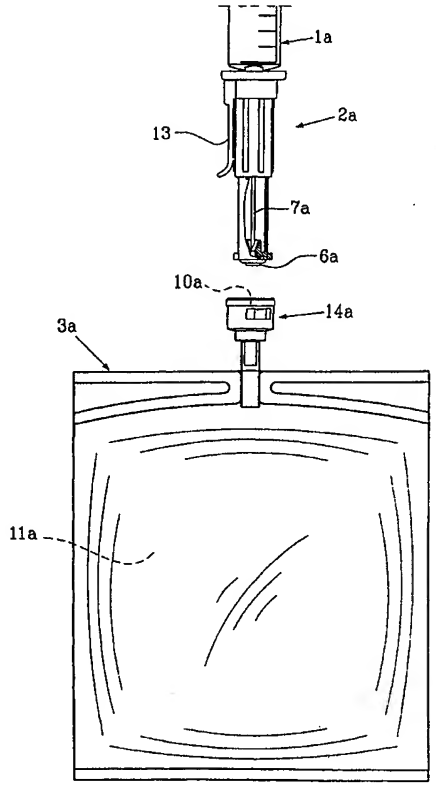
(57) Abstract

The invention relates to an assembly, a method, and a gas container for sterile or aseptic handling. The assembly comprises a coupling member (2a) for, towards the environment, gas and liquid–impermeable connection to a syringe (1a), a bottle connector for, towards the environment, gas and liquid–impermeable connection to a bottle having a seal, a first injection needle (7a) which is encapsulated when in a transport position, and a pressure compensating means. When coupled together, the coupling member and the bottle connector create, towards the environment, a gas and liquid–impermeable connection for transport of liquid and/or gas between the syringe and the bottle. The assembly further comprises a gas container (3a) with a connecting portion (14a), which during coupling to the coupling member creates, towards the environment, a gas and liquid–impermeable connection for transport of gas and/or liquid between the gas container and the syringe. The gas container contains gas which has been sterilised inside the gas container, and can increase in volume when being filled and decrease in volume when being emptied. The invention can be implemented for sterile or aseptic handling of drugs, fluids, or medical waste.



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Title

Arrangement, method and gas container for sterile or aseptic handling.

Technical field

The present invention relates to an assembly and a method for sterile or aseptic handling. The invention further relates to a gas container for use in the method. The invention can be implemented for sterile or aseptic preparation or handling of drugs intended for e.g. injection or infusion, or for sterile or aseptic handling of different fluids for use within medicine or diagnostics. The invention can also be implemented when handling medical waste.

Background of the invention

When preparing drugs, intended for e.g. injection or infusion, demands are made on aseptic conditions. In order to achieve such conditions when preparing drugs, for example in hospitals and pharmacies, special safety boxes or cabinets in a clean room environment normally are utilised.

One reason why the preparation is performed in clean rooms and special safety boxes is that sterile or aseptic air is needed, for example when a syringe furnished with an injection needle is used in order to aspirate a drug from a sealed, filled drug or injection bottle. In such a method, initially the syringe is filled with air, whereafter the injection needle of the syringe is run through the seal of the drug or injection bottle. Thereafter, the air inside the syringe is injected into the bottle, whereafter the drug is aspirated into the syringe. After this, the injection needle is withdrawn from the seal of the bottle, and the now drug-filled syringe can be utilised for further handling and/or for administration to a patient.

Accordingly, when performing preparation in accordance with what has been described above, air from the environment will replace the drug which is aspirated from the bottle or bottles. Therefore, it is important that the surrounding air is very clean, so that contamination does not arise and gives infections or other problems to a patient which is to be treated with the prepared drug. Furthermore, it is of course desirable to avoid that a drug in a bottle containing several doses is contaminated

from the environment via the air utilised for the preparation.

Therefore, it has been suggested previously that sterile air for aseptic preparation of drugs should be provided in a special container, out of which the air needed for the preparation can be drawn.

Accordingly, for example US 5,017,186 discloses an apparatus comprising a container with sterile pressurised air and a vessel for use when performing drug injections. By means of providing means for communication between the container with sterile air and the vessel, a charge of sterile air with a measured low pressure can be transferred from the container to the vessel. The vessel is provided with means for sealing the container after reception of the charge of sterile air from the container, and has air-impermeable walls and an aperture sealed by a puncturable, self-sealing closure. According to US 5,017,186, the vessel has substantially rigid walls, which for example can be of glass or acrylic plastic. The means for communication, between the container with sterile pressurised air and vessels which are to be filled with sterile air, comprises a coupling which is adapted to the type of vessels which are to be filled, a pressure gauge, and a valve. According to an alternative embodiment of what is disclosed in US 5,017,186, a vessel filled with sterile air together with a drug bottle with an injectable drug are provided in a tandem package.

Recently, also another problem in connection with drug preparation and other similar handling has been observed. It has been found that medical and pharmacological staff can be exposed to drugs or solvents in the ambient air while performing drug preparation. This problem is particularly serious when the preparation of e.g. cytotoxins is concerned. Cytotoxins have been reported to constitute a working environment problem when they escape into the environment. Antiviral drugs, antibiotics and radiopharmaceuticals are other drugs which can create working environment problems.

The previously known solutions for sterile or aseptic handling can be perceived as being associated with certain problems.

Sterile rooms, for instance, require a lot of space and are, furthermore, associated with high costs. Recently, it has been discovered that safety boxes in accordance with the present technology

provide an insufficent environmental protection. It has been discovered that, for example, cytotoxins are evaporated already at room temperature. Safety boxes in accordance with the present technology are provided with filters for filtration of circulating air and exhaust air. This type of filters are intended to trap aerosols and particles, but are not able to trap evaporated substances, something which is a known fact amongst manufacturers of safety boxes. Aerosols, which initially are trapped in the filters, can as time goes on transform into gas phase and be liberated.

The fact that the offered protection is insufficient is evident from, amongst other things, a study performed by Dr. Thomas H. Connor, University of Texas, Houston, U.S.A. This study was published in the "American Journal of Health - System Pharmacists", July 15, 1999. In an article by Paul J. M. Sessink and Rob P. Bos in the journal "Drug Safety 1999", April 20, pp. 347-359, the serious health hazards which can occur as a result of accidental exposure to cytotoxins are reported.

Special equipment for filling vessels with sterile air is space-consuming and impractical for medical care at home or in the field, for example in developing countries and in connection with wars and natural disasters. Furthermore, filling the pressurised air containers requires a supply of sterile air, and that the pressurised air containers are sterilised before use. Also the vessels which are to be filled with sterile air from a pressurised air container have to be sterilised before they are filled.

The use of vessels with rigid walls for providing sterile air requires that the sterile air is maintained under an overpressure, something which can render it difficult to fill a syringe with a desired amount of sterile air, since the overpressure tends to fill the syringe completely. Furthermore, disposable glass vessels for medical use are less desirable today, since a large proportion of the disposable medical waste nowadays is incinerated at a high temperature with heat recovery. Thereby, glass does not give any energy contribution but instead a large, undesired incineration residue which has to be brought to landfill. Glass vessels with sterile air under a relatively high pressure can result in a risk of glass fragments flying around in case a vessel accidentally is dropped onto the floor.

Furthermore, the existing systems for drug preparation which provide vessels with sterile air can be perceived as offering an insufficient protection against contamination when they are utilised in a non-sterile environment, since the injection needles of the utilised syringes are openly exposed to the non-sterile ambient air. Furthermore, such systems with unprotected injection needles can result in the staff being exposed to undesirably high drug or solvent contents in the air or, in the worst possible case, pricking themselves with an injection needle.

Summary of the invention

Accordingly, the first object of the present invention is to provide an assembly, which eliminates the above-mentioned problems with the prior art, and which ensures a sterile or aseptic handling of drugs or other fluids without any clean rooms or special equipment for filling sterilised air vessels, and which also eliminates the risk of staff being exposed to drugs or chemicals or pricking themselves on unprotected injection needles.

In accordance with claim 1, this first object of the invention is achieved by means of the assembly comprising a coupling member for, towards the environment, gas and liquid-impermeable connection to a syringe, a bottle connector for, towards the environment, gas and liquid-impermeable connection to a bottle having a seal, wherein the assembly further comprises a first injection needle, which is encapsulated when in a transport position, and a pressure compensating means. Thereby, the coupling member and the bottle connector are designed for creating a, towards the environment, gas and liquid-impermeable connection for transport of liquid and/or gas between the syringe and the bottle. According to the invention, the assembly further comprises a gas container having a connecting portion designed for creating a, towards the environment, gas and liquid-impermeable connection for transfer of gas and/or liquid between the gas container and the syringe, wherein the gas container contains gas which has been sterilised inside the gas container and is designed so that it can increase in volume when being filled and can decrease in volume when being emptied.

A second object of the present invention is to provide a method for sterile or aseptic handling which utilises the assembly according to the invention.

In accordance with claim 7, this second object of the invention is achieved by means of the method comprising to create a, towards the environment, gas and liquid-impermeable connection for gas and/or liquid transport between a syringe and a bottle by means of a first injection needle which is encapsulated when in a transport position. According to the invention, the method further comprises to create a, towards the environment, gas and liquid-impermeable connection for transport of gas and/or liquid between the syringe and a gas container by means of the first injection needle, wherein the gas container contains a gas which has been sterilised inside the gas container and increases in volume when being filled and decreases in volume when being emptied.

A third object of the present invention is to provide a particularly advantageous gas container for use in the method.

In accordance with claim 13, this third object of the invention is achieved by means of the gas container being constituted of a flexible bag of a substantially gas and liquid-impervious polymer material with a high chemical, radiation and temperature resistance, wherein the flexible bag contains gas which has been sterilised inside said bag under a pressure which at room temperature approaches atmospheric pressure, and wherein the bag has an opening covered by a substantially gas and liquid-impervious membrane which is puncturable with an injection needle and self-sealing.

Brief description of the drawings

In the following, the invention will be described in greater detail with reference to the attached drawings, in which

Fig. 1 shows a schematic side view of a partially cut away gas container, according to a preferred embodiment of the invention, together with a coupling member being part of the assembly according to the invention which comprises an encapsulated injection needle inside a first membrane.

Figs. 2A - 2J schematically illustrate a preferred embodiment of a method according to the invention implemented by means of an assembly according to the invention, wherein

Fig. 2A shows a schematic side view of a syringe connected to the coupling member in Fig. 1, together with the gas container in Fig. 1,

Fig. 2B shows a schematic side view of the parts shown in Fig. 2A coupled to each other and while aspirating sterilised air into the syringe from the gas container,

Fig. 2C shows a schematic side view of the syringe shown in Fig. 2B filled with sterilised air and together with a drug bottle having a seal, connected to a bottle connector comprising a second membrane and a pressure compensating means in the form of an essentially gas-impervious, expandable bladder,

Fig. 2D shows a schematic side view of the parts shown in Fig. 2C while coupling the coupling member to the bottle connector,

Fig. 2E shows a schematic side view of the parts in Fig. 2D at the stage when the encapsulated injection needle has penetrated the first and second membranes and the seal of the bottle,

Fig. 2F shows a schematic side view of the parts shown in Fig. 2E while injecting the sterilised air from the syringe via the bottle connector into the essentially gas-impervious bladder,

Fig. 2G shows a schematic side view of the parts shown in Fig. 2F, wherein the assembly has been turned upside down while aspirating a drug from the bottle into the syringe,

Fig. 2H schematically shows the assembly in Fig. 2G at the stage when the coupling member is released from the bottle connector, after the injection needle once again has been retracted into its encapsulated position behind the first membrane,

Fig. 2I schematically shows the assembly in Fig. 2H after the drug-filled syringe and the coupling member have been released from the bottle connector and the drug bottle,

Fig. 2J schematically shows the syringe with its connected coupling member ready for injection, wherein an adapter for coupling to an injection connection of a patient has been coupled to the coupling member.

Finally the drawings illustrate an alternative embodiment of the invention, wherein

Fig. 3 schematically shows a syringe with a coupling member coupled to a gas container according to the invention, at a stage when unused drug is injected into the air container for temporary storage until destruction can take place.

Detailed description of preferred embodiments

In the following, the invention will be described and when applicable with reference to the attached Figures 1 - 3.

According to a preferred embodiment, the assembly for sterile or aseptic handling comprises a syringe 1a, 1b, 1c, 1d, 1e, 1f, 1g, 1h, 1i, 1j; 1k of a type which is suitable for the purpose and known *per se*. The assembly further comprises a specially designed coupling member 2a, 2b, 2c, 2d, 2e, 2f, 2g, 2h, 2i, 2j; 2k, which comprises a first injection needle 7a, 7b, 7c, 7d, 7e, 7f, 7g, 7h, 7i, 7j; 7k, wherein one end of said coupling member is designed for, towards the environment, gas and liquid-impermeable connection to the syringe 1a-j; 1k.

In the described embodiment, the dimensions of the coupling member are adapted to the standardised dimensions of the tip of the syringe (not visible in the figures), in the form of a so-called Luer-coupling. Furthermore, in the described embodiment the coupling member comprises metal tongues (not visible in the Figures) which provide support around the tip of the syringe and which prevent the connection between the syringe and the coupling member from accidentally slipping apart. This ensures a stable connection and a perfect sealing. However, it is also conceivable with embodiments of the assembly according to the invention in which the connection between the syringe and the coupling member is designed in another suitable way, for example by means of a Luerlock-coupling, or another screw coupling.

In the described embodiment, the coupling member 2a-j; 2k is further provided with a substantially

gas and liquid-impervious first membrane 6a, 6c, 6i, which protects the first injection needle when this is in a "transport position". This "encapsulation" prevents staff from accidently pricking themselves with the injection needle and ensures that no hazardous drugs or chemicals escape into the working environment.

The first membrane 6a, 6c, 6i can be penetrated by the first injection needle 7b, 7e-g; 7k when this is brought into a penetration position. In Figures 2B, 2E, 2F, 2G and 2K, the first injection needle has been pressed into its penetration position. However, it is also conceivable with embodiments of the assembly according to the invention in which the same effect is achieved in another way than what is shown in the Figures, for example embodiments where the first membrane is penetrated by several injection needles, or where the injection needle is screwed into its penetration position.

The assembly according to the preferred embodiment further comprises a specially designed bottle connector 4c, 4d, 4e, 4f, 4g, 4 h, 4i for connection to a bottle 5c, 5d, 5e, 5f, 5g, 5h, 5i having a seal. As used herein, "bottle" refers to a drug vial or a chemical bottle of any previously known, standardised type, wherein it should be understood that the dimensions and the characteristics of the bottle connector have to be adapted to the type of bottle and seal (usually a rubber membrane) in question.

The bottle connector 4c-i further comprises a second injection needle (not visible in the Figures), which is designed for penetrating the seal of the bottle 5c-i, and for providing a, towards the environment, gas and liquid-impermeable connection. The bottle connector is designed in such a way that the neck of the bottle is clamped up in a safe way after connection.

In the described embodiment, the bottle connector 4c-i further comprises a substantially gas and liquid-impervious second membrane 8c, 8i and a pressure compenasating means 9c-i. In the described embodiment, the pressure compensating means is constituted of a substantially gas-impervious, expandable plastic bladder, which after the connection of the bottle connector stands in contact with the interiour of the bottle via the second injection needle which has penetrated the seal of the bottle. In case an overpressure is created inside the bottle, preferably gas will be pressed out into the plastic bladder so that the pressure inside the bottle is compensated. However, it is also conceivable with embodiments of the assembly according to the invention in which the pressure

compensation is accomplished in another suitable way.

In the described embodiment, the coupling member and the bottle connector are designed for being connectable with the first and second membranes in contact with each other in order to be penetrated by the first injection needle 7e-g in the penetration position, so that a, towards the environment, gas and liquid-impermeable connection for transport of liquid and/or gas is provided between the syringe 1e-g and the bottle 5e-g. In the described embodiment, the coupling is accomplished by means of suitably designed rotatable joints, but it is also conceivable with embodiments of the assembly in which the coupling is accomplished in another suitable, releasable way, for example by means of a snap-in coupling or a screw coupling.

In the preferred embodiment, the assembly further comprises a gas container 3a, 3b; 3k having a connecting portion 14a-b; 14k, comprising an opening covered by a third substantially gas and liquid-impervious membrane 10a, wherein the connecting portion is designed for being connectable to the coupling member 2b; 2k with the first membrane in contact with the third membrane and penetrated by the first injection needle 7b; 7k in the penetration position. In this way a, towards the environment, gas and liquid-impermeable connection for transport of gas and/or liquid between the gas container 3b; 3k and the syringe 1b; 1k is provided. The gas container 3a-b; 3k comprises a gas which has been sterilised inside the air container and is designed so that it can increase in volume when being filled and can decrease in volume when being emptied.

The fact that the gas container both can increase in volume and decrease in volume enables the container to be emptied without any risk of a vacuum being created inside the gas container, making it difficult to aspirate air. Nor is there, when using the gas container, any risk of an overpressure being created inside the gas container, leading to rupture of the container or to hazardous drugs or chemicals being pressed out into the working environment.

According to a preferred embodiment of the assembly according to the invention, the gas container 3a-b contains a gas 11 a-b which has been sterilised inside the gas container with the use of radiation treatment. Thereby, the radiation treatment can be accomplished with any suitable technique known *per se*. It is also conceivable with embodiments of the invention in which another suitable sterilisation treatment is utilised. Since the sterilisation of the gas takes place inside the gas

container, the need for separate steps in which the gas and containers for sterile gas are sterilised is eliminated.

In another advantageous embodiment of the assembly according to the invention, the gas container 3a-b contains sterilised or aseptic air 11a-b.

In another advantageous embodiment of the assembly according to the invention, the gas container 3k contains medical waste 12k which is to be brought to destruction. Thereby, the waste can comprise for example drug or solvent which has been left over, or even body fluids from a patient. This embodiment is particularly advantageous for medical care at home or in the field, where no destruction possibilities are available. Since the injection needles included in the assembly are "encapsulated" when in their transport positions, also the risk of the gas container accidentally being punctured, when it contains medical waste, is minimised.

In still another advantageous embodiment of the assembly according to the invention, the gas container 3a-b; 3k is constituted of a flexible bag of a substantially gas and liquid-impervious polymer material with high chemical, radiation and temperature resistance. Thereby, the flexible bag can be constituted of polyvinyl chloride plastic film, or of another polymer material with high durability and good combustion properties.

In the following, a preferred embodiment of a method for sterile or aseptic handling according to the invention will be described with reference to the attached figures 2A - 2J.

The method according to the preferred embodiment comprises to create a, towards the environment, gas and liquid-impermeable connection for gas and/or liquid transport between a syringe 1e-g and a bottle 5e-g by means of a first injection needle 7a-j; 7k, which is encapsulated when in a transport position. The method further comprises to create a, towards the environment, gas and liquid-impermeable connection for transport of gas and/or liquid between the syringe 1b; 1k and a gas container 3b; 3k by means of the first injection needle 7b; 7k, wherein the gas container contains a gas which has been sterilised inside the gas container and increases in volume when being filled and decreases in volume when being emptied.

In the described embodiment of the method, also a coupling member 2a-j; 2k is utilised, which comprises a substantially gas and liquid-impervious first membrane 6a, 6c, 6i covering the first injection needle when this is encapsulated in its transport position. Furthermore, the bottle connector 4c-i comprises a second injection needle which penetrates the seal of the bottle 5c-i and which is in contact with a pressure compensating means 9c-i. The assembly further comprises a, substantially gas and liquid-impervious, second membrane 8c, 8i. Thereby, the coupling member and the bottle connector are coupled together with the first and second membranes in contact with each other, wherein the first and second mebranes are penetrated by the first injection needle 7e-g when this is brought into a penetration position.

In the described embodiment of the method, the gas container 3a-b; 3k has an opening which is covered by a third, substantially gas and liquid-impervious, membrane 10a, which during coupling to the coupling member 2b; 2k stands in contact with the first membrane, wherein the first and third membranes are penetrated by the first injection needle 7b; 7k when this is brought into the penetration position.

In another advantageous embodiment of the method according to the invention, the gas container 3a-b contains gas 11a-b which has beed sterilised inside the gas container using radiation treatment. This embodiment provides the above-mentioned advantages that no separate sterilisations of gas and container are needed.

In still another advantageous embodiment of the method according to the invention, the gas container contains sterile or aseptic air, which is aspirated into the syringe 1b while the volume of the gas container 3b decreases.

In an alternative embodiment of the method, medical waste 12k which is to be brought to destruction is injected into the gas container 3k from the syringe 1k while the volume of the gas container 3k increases. However, it is also conceivable with embodiments of the invention in which other waste or unused material from sterile or aseptic handling is injected into the gas container.

In a particularly advantageous embodiment of the method according to the invention, the gas container 3a-b; 3k is constituted of a flexible bag of a substantially gas and liquid-impervious

polymer material with high chemical, radiation and temperature resistance.

In the following, a preferred embodiment of a gas container for sterile or aseptic handling by means of the method according to the invention will be described.

In the preferred embodiment of the gas container 3a-b; 3k, it is constituted of a flexible bag of a substantially gas and liquid-impervious polymer material with high chemical, radiation and temperature resistance, wherein the flexible bag contains gas 11a-b, which has been sterilised inside the bag, under a pressure which at room temperature approaches atmospheric pressure, wherein the bag has an opening covered by a substantially gas and liquid-impervious membrane 10a which is puncturable with an injection needle and self-sealing. In the preferred embodiment, the membrane of the gas container is intended to be in contact with a corresponding membrane 6a of a coupling member 2a when emptying or filling the bag. However, it is also conceivable that the gas container according to the invention, in a gas and liquid-impermeable way, is coupled to a component of a system for sterile or aseptic handling which has another design than the coupling member described herein.

In a particularly advantageous embodiment of the gas container according to the invention, the gas 11a-b is sterile or aseptic air intended for sterile or aseptic handling of drugs or fluids.

It should be understood that the present invention by no means is limited to what has been described in the foregoing in connection with the preferred embodiments, or to what is shown in the attached drawings, but the scope of the invention is defined by the attached claims.

Accordingly, it can be mentioned that the above-described coupling member 2a-j; 2k advantageously is provided with a locking device which prevents the first injection needle from accidentally being caused to penetrate the first membrane. In the attached Fig. 1, the locking device is designated with the reference numeral 13, which for reasons of simplicity has been omitted in the remaining Figures. However, it is also conceivable with embodiments of the invention in which the locking device has another design, or where no actual locking device is present.

Furthermore, within the scope of the invention as defined by the attached claims, it is also

conceivable with less advantageous embodiments where no actual coupling member or no actual bottle connector is present.

Claims

1. An assembly for sterile or aseptic handling, comprising a coupling member (2a-j; 2k) for, towards the environment, gas and liquid-impermeable connection to a syringe (1a-j; 1k), a bottle connector (4c-i) for, towards the environment, gas and liquid-impermeable connection to a bottle (5c-i) having a seal, wherein the assembly further comprises a first injection needle (7a-j; 7k), which is encapsulated when in a transport position, and a pressure compensating means (9c-i), wherein the coupling member and the bottle connector are designed for creating a, towards the environment, gas and liquid-impermeable connection for transport of liquid and/or gas between the syringe (1e-g) and the bottle (5e-g), c h a r a c t e r i s e d i n that the assembly further comprises a gas container (3a-b; 3k) having a connecting portion (14a-b; 14k) designed for creating a, towards the environment, gas and liquid-impermeable connection for transport of gas and/or liquid between the gas container (3b; 3k) and the syringe (1b; 1k) when being coupled to the coupling member (2b; 2k), wherein the gas container contains gas which has been sterilised inside the gas container and is designed so that it can increase in volume when being filled and decrease in volume when being emptied.

2. An assembly according to claim 1,
wherein the coupling member (2a-j; 2k) comprises a substantially gas and liquid-impervious first membrane (6a, 6c, 6i) covering the first injection needle when encapsulated in the transport position, and the bottle connector (4c-i) comprises a second injection needle for penetrating the seal of the bottle (5c-i) and a substantially gas and liquid-impervious second membrane (8c, 8i) and a pressure compensating means (9c-i), wherein the coupling member and the bottle connector are designed for being coupled together with the first and second membranes in contact with each other so that said first and second membranes can be penetrated by the first injection needle (7e-g) brought into a penetration position, c h a r a c t e r i s e d i n that the connecting portion (14a-b; 14k) has an opening which is covered by a third, substantially gas and liquid-impervious, membrane (10a) which during coupling to the coupling member (2b; 2k) stands in contact with the first membrane, so that said first and third membranes can be penetrated by the first injection needle (7b; 7k) brought into the penetration position.

3. An assembly according to claim 1 or 2,
characterised in that the gas container (3a-b) contains a gas (11a-b) which has been sterilised inside the gas container with the use of radiation treatment.

4. An assembly according to claim 1, 2 or 3,
characterised in that the gas container contains sterilised or aseptic air.

5. An assembly according to any one of the preceding claims,
characterised in that the gas container (3k) contains medical waste (12k) which is to be brought to destruction.

6. An assembly according to any one of the preceding claims,
characterised in that the gas container (3a-c; 3k) is constituted of a flexible bag of substantially gas and liquid-impervious polymer material with high chemical, radiation and temperature resistance.

7. A method for sterile or aseptic handling, comprising to create a, towards the environment, gas and liquid-impermeable connection for gas and/or liquid transport between a syringe (1e-g) and a bottle (5e-g) by means of a first injection needle (7a-j; 7k) which is encapsulated when in a transport position , characterised in that the method further comprises to create a, towards the environment, gas and liquid-impermeable connection for transport of gas and/or liquid between the syringe (1b; 1k) and a gas container (3b; 3k) by means of the first injection needle (7b; 7k), wherein the gas container comprises a gas (11b) which has been sterilised inside the gas container and increases in volume when being filled and decreases in volume when being emptied.

8. A method according to claim 7, wherein a coupling member (2a-j; 2k) comprises a substantially gas and liquid-impervious membrane (6a, 6c, 6i) covering the first injection needle when encapsulated in the transport position, and the bottle connector (4c-i) comprises a substantially gas and liquid-impervious second membrane (8c, 8i) and a second injection needle which penetrates the seal of the bottle (5c-i) and stands in contact with a pressure compensating means (9c-i), and wherein the coupling member and the bottle connector are coupled together with

the first and second membranes in contact with each other and said first and second membranes are penetrated by the first injection needle (7e-g) brought into a penetration position,

c h a r a c t e r i s e d i n that the gas container (3a-b; 3k) has an opening covered by a third, substantially gas and liquid-impervious, membrane (10a) which during coupling to the coupling member (2b; 2k) is in contact with the first membrane, wherein said first and third membranes are penetrated by the first injection needle (7b; 7k) when this is brought into the penetration position.

9. A method according to claim 7 or 8,

c h a r a c t e r i s e d i n that the gas container (3a-b) contains gas (11a-b) which has been sterilised inside the gas container with the use of radiation treatment.

10. A method according to claim 7, 8 or 9,

c h a r a c t e r i s e d i n that the gas container contains sterile of aseptic air which is aspirated into the syringe (1b) while the volume of the gas container (3b) decreases.

11. A method according to any one of claims 7 - 10,

c h a r a c t e r i s e d i n that medical waste (12k) which is to be brought to destruction is injected into the gas container (3k) from the syringe (1k) while the volume of the gas container (3k) increases.

12. A method according to any one of claims 7 - 11,

c h a r a c t e r i s e d i n that the gas container (3a-b; 3k) is constituted of a flexible bag of a substantially gas and liquid-impervious polymer material with high chemical, radiation and temperature resistance.

13. A gas container for sterile or aseptic handling by means of a method according to any one of claims 7 - 12, c h a r a c t e r i s e d i n that the gas container (3a-b; 3k) is constituted of a flexible bag of a substantially gas and liquid-impervious polymer material with high chemical, radiation and temperature resistance, and that the flexible bag contains gas (11a-b) which has been sterilised inside said bag under a pressure which at room temperature approaches atmospheric pressure, and that the bag has an opening covered by a substantially gas and liquid-impervious membrane (10a) which is puncturable with an injection needle and self-sealing.

14. A gas container according to claim 13,
characterised in that the substantially gas and liquid-impervious membrane (10a), which is puncturable with a injection needle and self-sealing, is intended to be in contact with a corresponding membrane (6a) of a coupling member (2a) when emptying or filling the bag.

15. A gas container according to claim 13 or 14,
characterised in that the gas (11a-b) is sterile or aseptic air intended for sterile or aseptic handling of drugs or fluids.

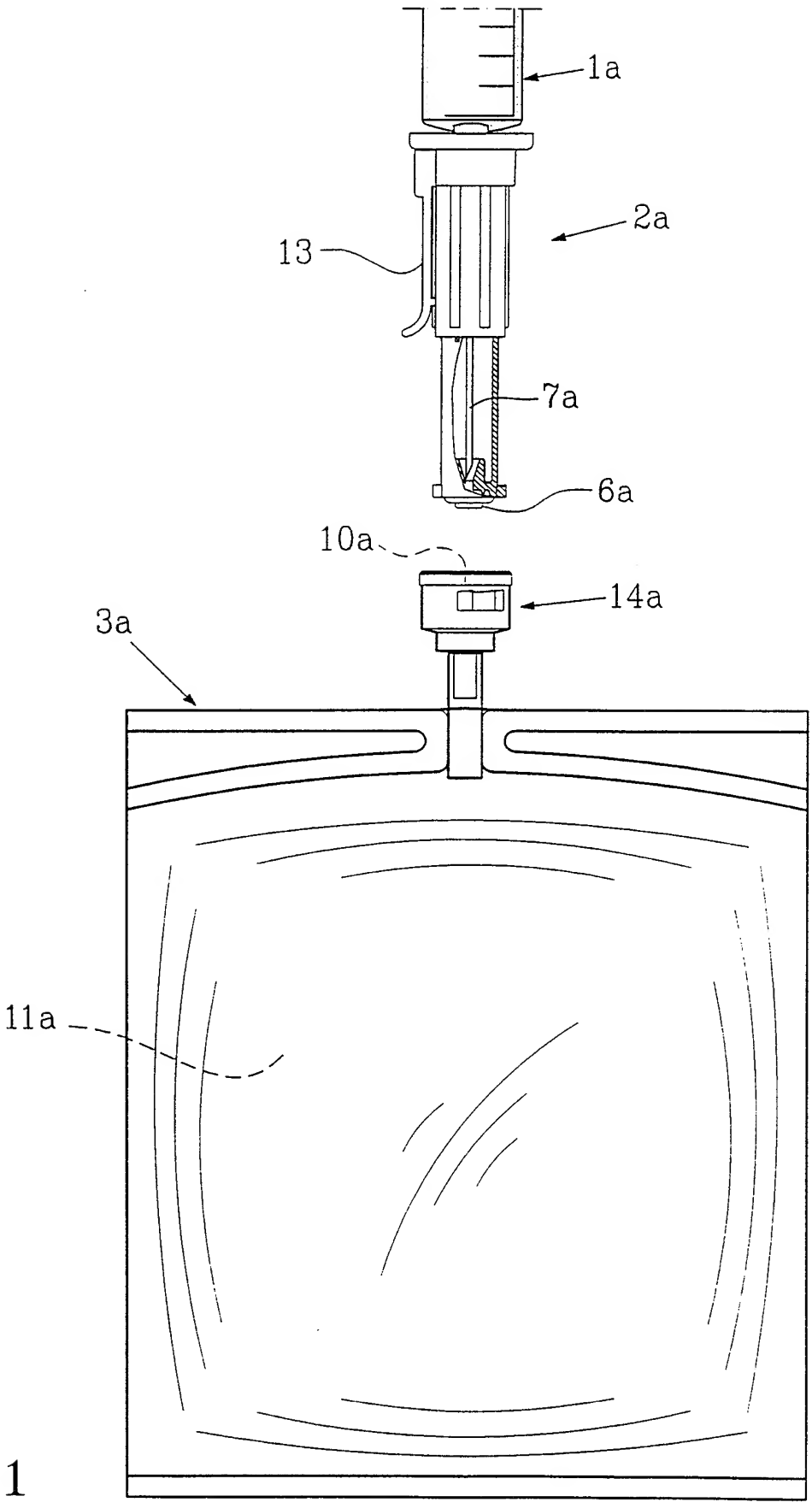

FIG. 1

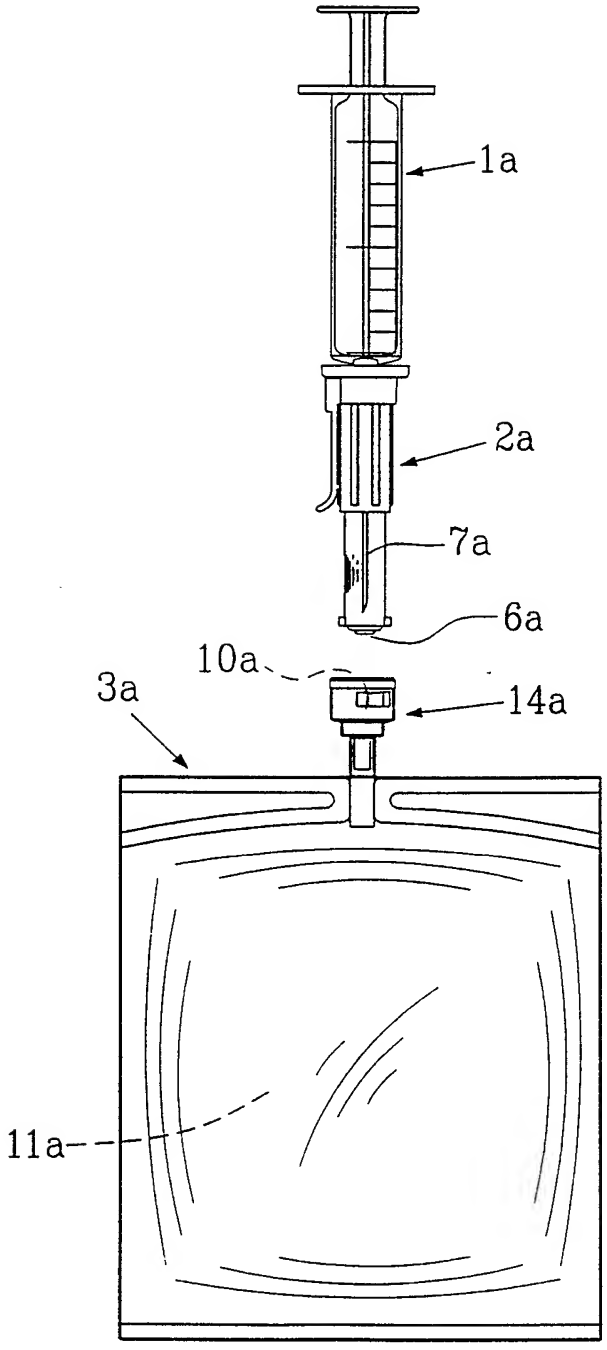

FIG.2a

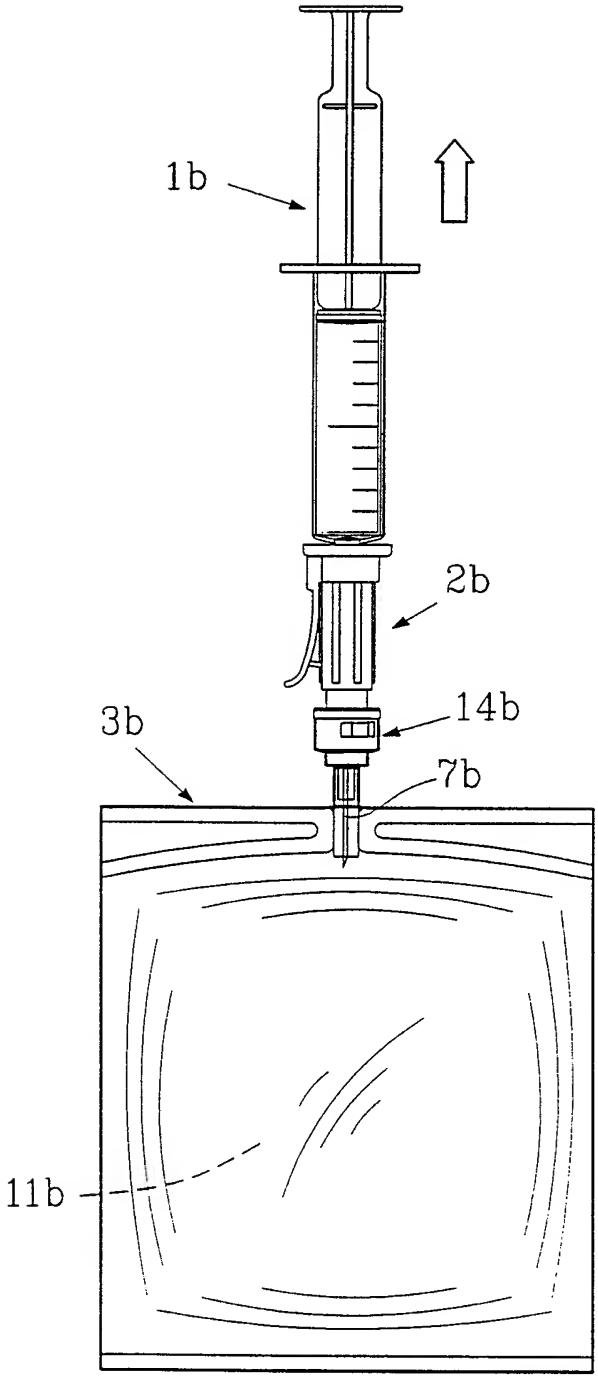

FIG.2b

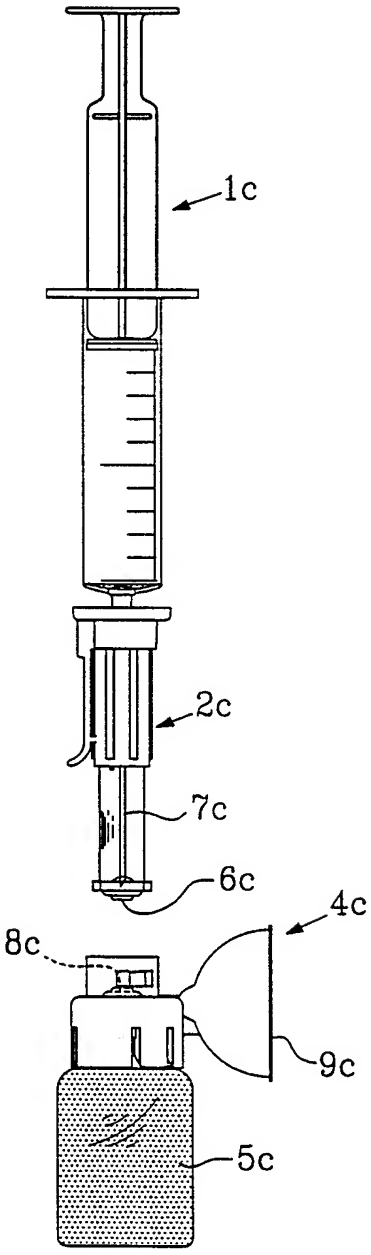

FIG.2c

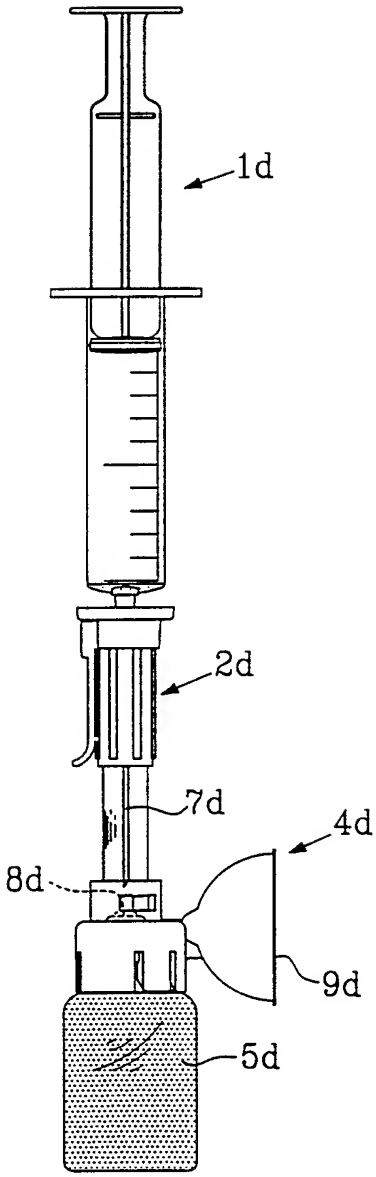

FIG.2d

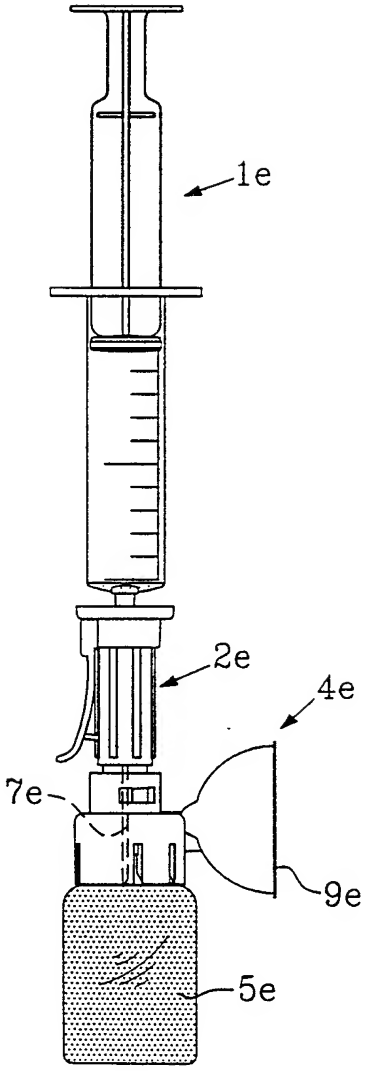

FIG.2e

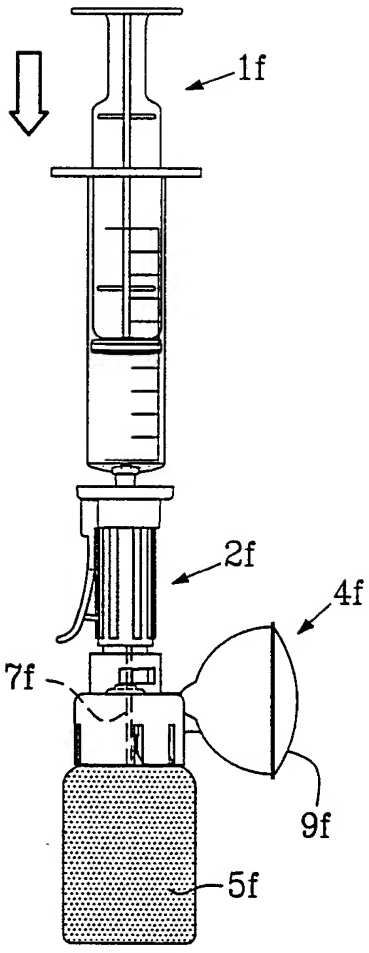

FIG.2f

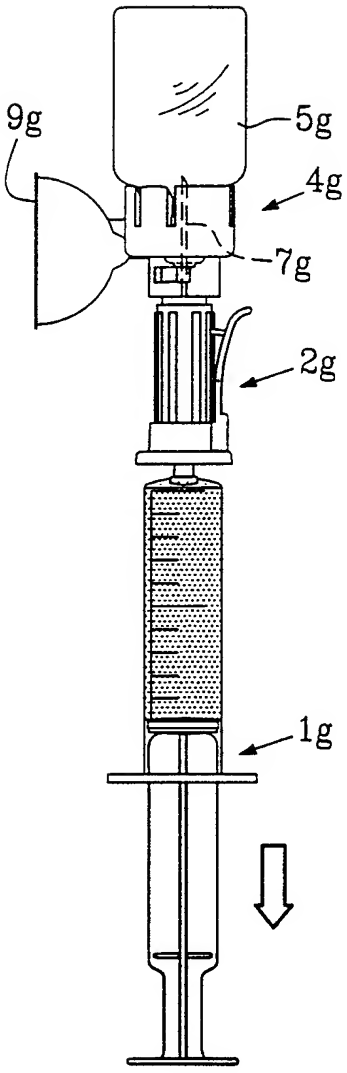

FIG.2g

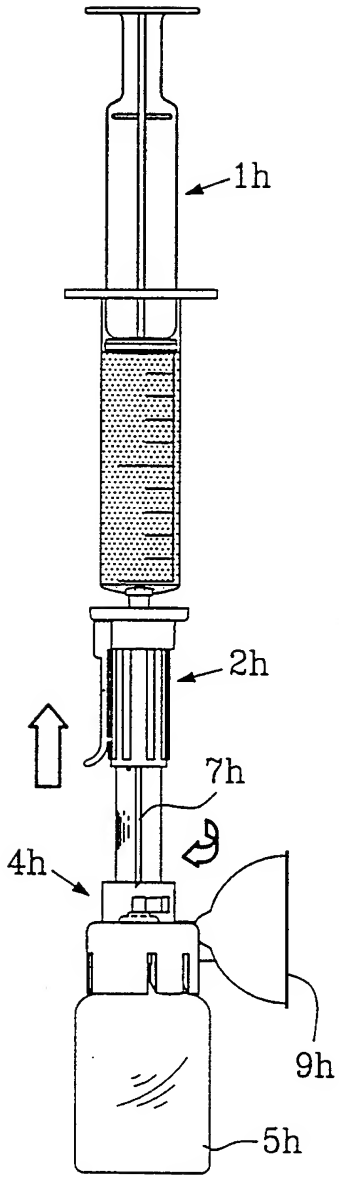

FIG.2h

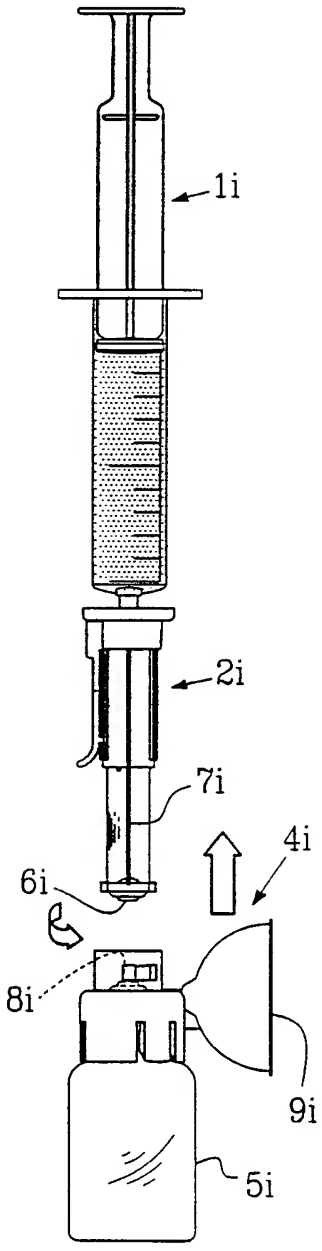

FIG.2i

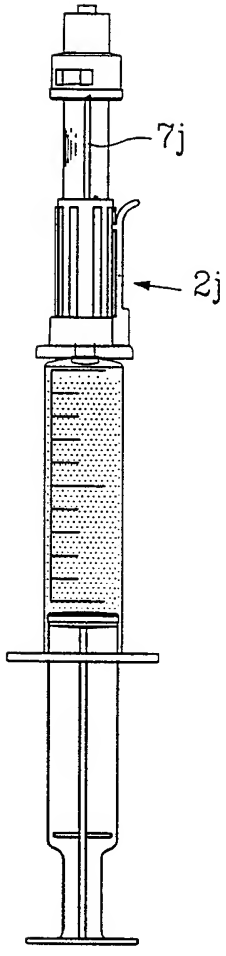

FIG.2j

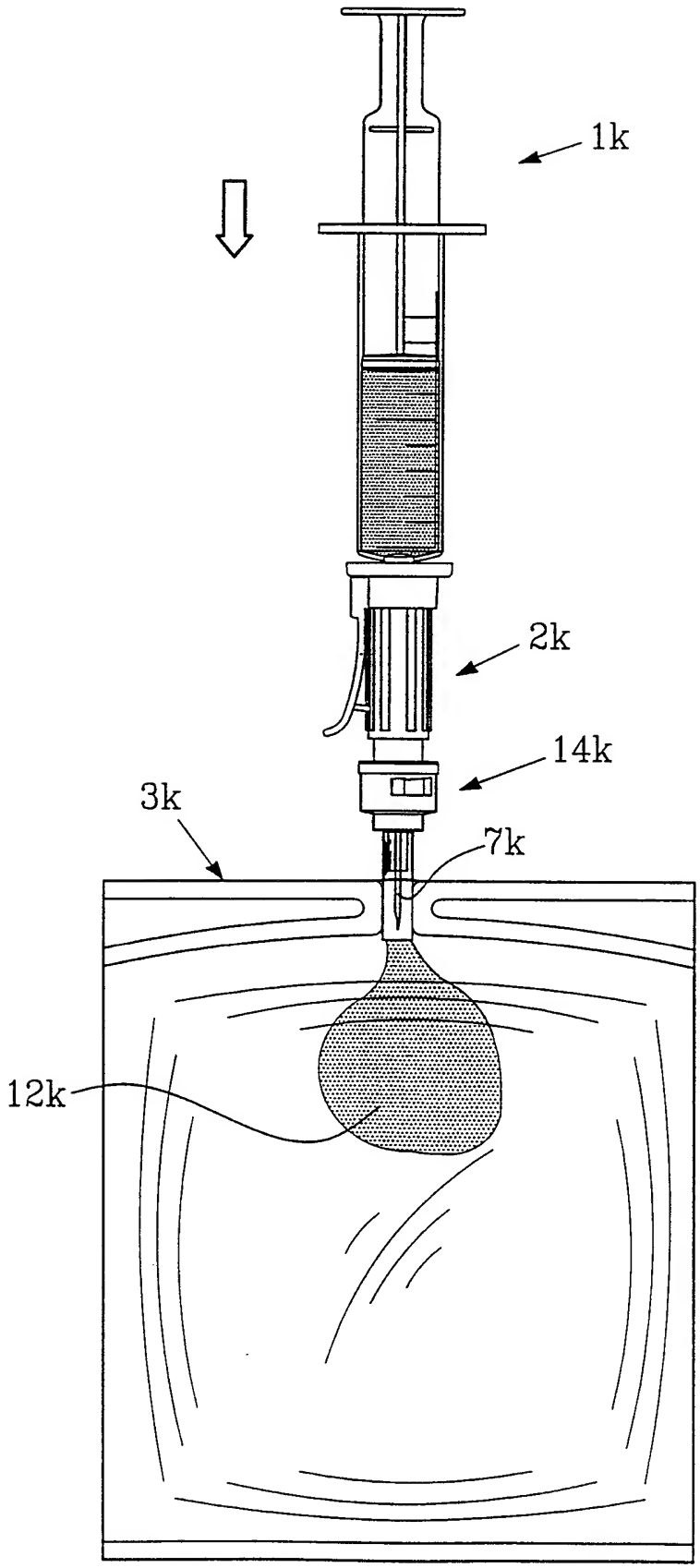

FIG.3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99/02144

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 5/00, A61J 1/005
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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M, A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 4645073 A (G. HOMAN), 24 February 1987 (24.02.87), column 2, line 33 - line 36; column 3, line 44 - line 46, abstract	1-15
A	US 4576211 A (L. VALENTINI ET AL.), 18 March 1986 (18.03.86), figure 1, abstract	1-15
A	US 5807374 A (R.J. CAIZZ AT AL.), 15 Sept 1998 (15.09.98), figure 2, abstract	1-15

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2 March 2000	15 -03- 2000
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International application No.
PCT/SE 99/02144

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5195987 A (K.D. KARPIAK), 23 March 1993 (23.03.93), figure 1, abstract ---	1-15
A	US 5102406 A (V.A. ARNOLD), 7 April 1992 (07.04.92), figure 2, abstract ---	1-15
A	US 4516977 A (R. HERBERT), 14 May 1985 (14.05.85), figure 1, abstract --- --------	1-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.
PCT/SE 99/02144

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4564054 A	14/01/86	AT 36955 T	15/09/88
		AT 57612 T	15/11/90
		AU 569900 B	25/02/88
		AU 575814 B	11/08/88
		AU 2653784 A	18/12/84
		AU 3017584 A	18/12/84
		BR 8407302 A	25/03/86
		CA 1215945 A	30/12/86
		DE 3473823 A	13/10/88
		DK 23885 A	20/03/85
		DK 23985 A	12/03/85
		DK 159866 B,C	24/12/90
		DK 161181 B,C	10/06/91
		EP 0126718 A	28/11/84
		EP 0165926 A,B	02/01/86
		SE 0165926 T3	
		EP 0176511 A,B	09/04/86
		SE 0176511 T3	
		FI 852454 A	20/06/85
		FI 852455 A	20/06/85
		JP 5050293 B	28/07/93
		JP 60501294 T	15/08/85
		JP 60501342 T	22/08/85
		NO 850235 A	18/01/85
		NZ 207354 A	29/02/88
		SE 434700 B,C	13/08/84
		SE 8301176 D	00/00/00
		US 4673404 A	16/06/87
		WO 8404672 A	06/12/84
		WO 8404673 A	06/12/84
		ZA 8401591 A	28/11/84
US 4645073 A	24/02/87	NONE	

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.
PCT/SE 99/02144

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4576211 A	18/03/86	AU 574758 B	14/07/88
		AU 3848985 A	29/08/85
		BE 901699 A	29/05/85
		CA 1244804 A	15/11/88
		CH 663156 A,B	30/11/87
		CS 264118 B	13/06/89
		CS 8501160 A	16/09/88
		DE 3503460 A	05/09/85
		DK 47185 A	25/08/85
		DK 164205 B,C	25/05/92
		FI 81499 B,C	31/07/90
		FI 850418 A	25/08/85
		FR 2560049 A,B	30/08/85
		GB 2154562 A,B	11/09/85
		GR 850271 A	28/05/85
		JP 1588629 C	19/11/90
		JP 2014852 B	10/04/90
		JP 60222059 A	06/11/85
		NL 8500512 A	16/09/85
		NZ 210993 A	12/02/88
		PT 79923 A,B	01/03/85
		SE 463238 B,C	29/10/90
		SE 8500420 A	25/08/85
		SU 1308184 A	30/04/87
US 5807374 A	15/09/98	AU 7859798 A	25/02/99
		EP 0896826 A	17/02/99
		JP 11114064 A	27/04/99
		US 5928215 A	27/07/99
US 5195987 A	23/03/93	NONE	
US 5102406 A	07/04/92	AU 5639290 A	07/01/91
		CA 2057015 A	03/12/90
		GB 2248782 A	22/04/92
		JP 4505403 T	24/09/92
		WO 9014798 A	13/12/90

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.
PCT/SE 99/02144

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4516977 A	14/05/85	AT 47306 T	15/11/89
		AU 559597 B	12/03/87
		AU 2429584 A	23/08/84
		BR 8400701 A	25/09/84
		DD 217146 A	09/01/85
		DE 3305365 A,C	06/09/84
		DK 72084 A	18/08/84
		DK 157391 B,C	02/01/90
		EP 0119469 A,B	26/09/84
		SE 0119469 T3	
		ES 529854 A	01/06/86
		FI 82597 B,C	31/12/90
		FI 840495 A	18/08/84
		HR 920390 B	28/02/99
		JP 1813026 C	27/12/93
		JP 5018582 B	12/03/93
		JP 59209352 A	27/11/84
		NO 840585 A	20/08/84
		YU 28084 A	30/06/86
		ZA 8401131 A	31/10/84

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A1

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(30) Priority Data:
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(71) Applicant *(for all designated States except US)*: CARMEL PHARMA AB [SE/SE]; P.O. Box 5352, S–402 28 Göteborg (SE).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: WESSMAN, Göran [SE/SE]; Örgryte Stomgata 14 B, S–412 67 Göteborg (SE).

(74) Agent: GÖTEBORGS PATENTBYRÅ DAHLS AB; Sjöporten 4, S–417 64 Göteborg (SE).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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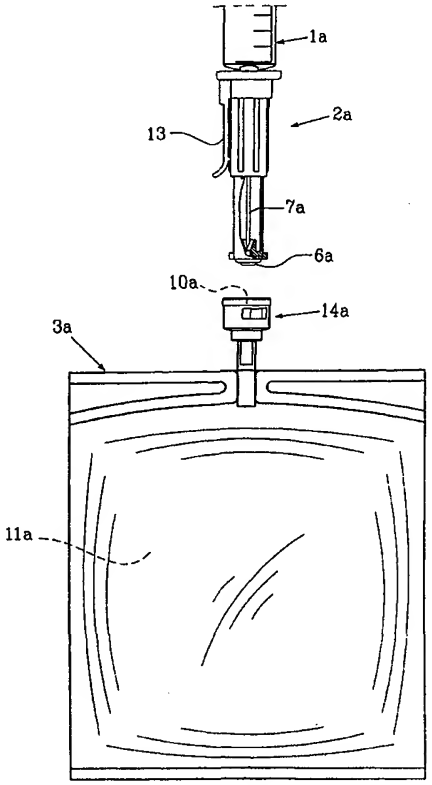
(54) Title: ARRANGEMENT, METHOD AND GAS CONTAINER FOR STERILE OR ASEPTIC HANDLING

(57) Abstract

The invention relates to an assembly, a method, and a gas container for sterile or aseptic handling. The assembly comprises a coupling member (2a) for, towards the environment, gas and liquid–impermeable connection to a syringe (1a), a bottle connector for, towards the environment, gas and liquid–impermeable connection to a bottle having a seal, a first injection needle (7a) which is encapsulated when in a transport position, and a pressure compensating means. When coupled together, the coupling member and the bottle connector create, towards the environment, a gas and liquid–impermeable connection for transport of liquid and/or gas between the syringe and the bottle. The assembly further comprises a gas container (3a) with a connecting portion (14a), which during coupling to the coupling member creates, towards the environment, a gas and liquid–impermeable connection for transport of gas and/or liquid between the gas container and the syringe. The gas container contains gas which has been sterilised inside the gas container, and can increase in volume when being filled and decrease in volume when being emptied. The invention can be implemented for sterile or aseptic handling of drugs, fluids, or medical waste.



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International application No.
PCT/SE 99/02144

A. CLASSIFICATION OF SUBJECT MATTER

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Minimum documentation searched (classification system followed by classification symbols)

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Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Joni Saveler 8 782 25 00

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International application No.
PCT/SE 99/02144

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4564054 A	14/01/86	AT 36955 T	15/09/88
		AT 57612 T	15/11/90
		AU 569900 B	25/02/88
		AU 575814 B	11/08/88
		AU 2653784 A	18/12/84
		AU 3017584 A	18/12/84
		BR 8407302 A	25/03/86
		CA 1215945 A	30/12/86
		DE 3473823 A	13/10/88
		DK 23885 A	20/03/85
		DK 23985 A	12/03/85
		DK 159866 B,C	24/12/90
		DK 161181 B,C	10/06/91
		EP 0126718 A	28/11/84
		EP 0165926 A,B	02/01/86
		SE 0165926 T3	
		EP 0176511 A,B	09/04/86
		SE 0176511 T3	
		FI 852454 A	20/06/85
		FI 852455 A	20/06/85
		JP 5050293 B	28/07/93
		JP 60501294 T	15/08/85
		JP 60501342 T	22/08/85
		NO 850235 A	18/01/85
		NZ 207354 A	29/02/88
		SE 434700 B,C	13/08/84
		SE 8301176 D	00/00/00
		US 4673404 A	16/06/87
		WO 8404672 A	06/12/84
		WO 8404673 A	06/12/84
		ZA 8401591 A	28/11/84
US 4645073 A	24/02/87	NONE	

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.
PCT/SE 99/02144

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4576211 A	18/03/86	AU 574758 B	14/07/88
		AU 3848985 A	29/08/85
		BE 901699 A	29/05/85
		CA 1244804 A	15/11/88
		CH 663156 A,B	30/11/87
		CS 264118 B	13/06/89
		CS 8501160 A	16/09/88
		DE 3503460 A	05/09/85
		DK 47185 A	25/08/85
		DK 164205 B,C	25/05/92
		FI 81499 B,C	31/07/90
		FI 850418 A	25/08/85
		FR 2560049 A,B	30/08/85
		GB 2154562 A,B	11/09/85
		GR 850271 A	28/05/85
		JP 1588629 C	19/11/90
		JP 2014852 B	10/04/90
		JP 60222059 A	06/11/85
		NL 8500512 A	16/09/85
		NZ 210993 A	12/02/88
		PT 79923 A,B	01/03/85
		SE 463238 B,C	29/10/90
		SE 8500420 A	25/08/85
		SU 1308184 A	30/04/87
US 5807374 A	15/09/98	AU 7859798 A	25/02/99
		EP 0896826 A	17/02/99
		JP 11114064 A	27/04/99
		US 5928215 A	27/07/99
US 5195987 A	23/03/93	NONE	
US 5102406 A	07/04/92	AU 5639290 A	07/01/91
		CA 2057015 A	03/12/90
		GB 2248782 A	22/04/92
		JP 4505403 T	24/09/92
		WO 9014798 A	13/12/90

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.
PCT/SE 99/02144

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4516977 A	14/05/85	AT 47306 T	15/11/89
		AU 559597 B	12/03/87
		AU 2429584 A	23/08/84
		BR 8400701 A	25/09/84
		DD 217146 A	09/01/85
		DE 3305365 A,C	06/09/84
		DK 72084 A	18/08/84
		DK 157391 B,C	02/01/90
		EP 0119469 A,B	26/09/84
		SE 0119469 T3	
		ES 529854 A	01/06/86
		FI 82597 B,C	31/12/90
		FI 840495 A	18/08/84
		HR 920390 B	28/02/99
		JP 1813026 C	27/12/93
		JP 5018582 B	12/03/93
		JP 59209352 A	27/11/84
		NO 840585 A	20/08/84
		YU 28084 A	30/06/86
		ZA 8401131 A	31/10/84